INFORMED CONSENT IN THE DEVELOPMENT OF CASE STUDIES

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Abstract

The informed consent of human subjects is a fundamental principle of research ethics. Informed consent is a core principle in international codes of research ethics, as well as in discipline-specific guides to the ethical conduct of research. Scholars developing case reports or case studies need to be aware of the considerations that are involved in assuring that the principle of informed consent is honored, whether or not the case study is construed as a research project. This paper describes basic issues involved in the application of the principle of informed consent, with particular attention to those considerations that apply in the development of case reports or case studies.

KEY WORDS: Research ethics, informed consent, human subjects, confidentiality, autonomy, cross-cultural research

INTRODUCTION

Case studies are commonly used as pedagogical tools to illustrate and clarify principles and their application. Development of case studies often involves collecting information from people, and such work should be guided by an understanding of research ethics. Indeed, among the many domains where case studies are useful tools is the teaching of ethics itself (including research ethics, legal ethics, medical ethics, and business ethics), as well as in teaching the regulatory policies and procedures designed to assure ethical conduct. Developers of case studies should adhere to high ethical standards in developing case studies, whether these are intended as research studies or as pedagogical tools.

A fundamental principle in research ethics is that of "informed consent." Informed consent is the principle that subjects should be able to determine whether and in what ways they will provide information, submit to manipulation, and forgo privacy, with this self-determination based on clear, understandable information about the nature of the project, of the participant’s role, and of any benefits or risks.

In some countries, including the United States, case studies that meet the regulatory definition of research are subject to formal review by an institutional review board, and these formal reviews include reviews of informed consent procedures. However, informed consent is relevant whether or not the case study meets the formal definition of research (discussed below). Thus, while the principles reviewed below derive primarily from discussion of research ethics, they are also relevant to case studies that are construed solely as pedagogical tools rather than as contributions to generalizable knowledge. Such case studies may be "scholarship" without meeting the formal definition of research, and issues of informed consent are relevant in almost all scholarly work involving human participants.
INFORMED CONSENT IN CODES OF RESEARCH ETHICS

Historically, the importance of informed consent became painfully and scandalously apparent following World War II, when the horrific crimes of Nazi researchers came to light. This led to the Nuernburg Code of 1949, whose first directive is “The voluntary consent of the human subject is absolutely essential.” The Nuernberg Code was reinterpreted and elaborated by the World Medical Association in the Declaration of Helsinki [1964]. In the United States, press reports and public indignation over the Tuskegee syphilis study, which was conducted without informed consent, spurred Congress to form a National Commission for the Protection of Human Subjects. The Commission produced the Belmont Report [1979], which is an essential source for anyone who conducts research with human subjects. The Belmont Report identified three core ethical principles: respect for persons, beneficence, and justice. Considerations of how and when informed consent should be obtained often make reference to the Belmont Report principles.

Because the events that led to formalizations of protections for human subjects were sometimes horrific ones, scholars can correctly note that violations of the principle of informed consent in Nazi concentration camps bear little relationship to the work typically done by academic scholars preparing case studies. Similarly, some scholars assume that ethical standards were developed for biomedical researchers and therefore do not apply to work in other domains. It is therefore essential to recognize that the ethical principles identified in the Belmont report are not specific to any particular domain of study. The principles apply broadly not only to research, the domain for which they were developed, but also to any other activity that could potentially violate the privacy, autonomy, well-being, or fair treatment of people who participate or provide information. Thus, scholars who prepare case studies need to be aware of the ethical issues and particularly of the role that informed consent plays in the ethical collection of information, so they can make sound, informed judgments about whether and how informed consent should be obtained.

“BELMONT” PRINCIPLES

While the Belmont Report was developed specifically to provide a framework for the ethical conduct of research, the Belmont principles are useful guidelines for people who are writing case studies solely for pedagogical purposes, as well as for those whose work more obviously constitutes research. The three basic principles are:

Respect for Persons
The autonomy of people who are providing information or are otherwise being studied must be respected. Usually, this means that people participate voluntarily, and they reach the decision to participate only after having been adequately informed about the nature of the project. Application of this principle requires making judgments about whether consent is truly voluntary, or whether there has been undue coercion. For example, if a researcher is in a relationship that involves power (e.g., student-teacher, employer-employee), there may be implicit coercion that renders a decision less than fully voluntary. One problem with the attempt to apply this principle universally is that there are large cultural differences in the extent to which individuals are viewed as autonomous agents; the implications of these different views of autonomy are discussed later in this paper, in the context of cross-cultural studies. An additional facet of the principle of “respect for persons” is that people with diminished autonomy (e.g., children, prisoners, people with certain disabilities) must be accorded special protection.

Beneficence
Since Hippocrates, the principle of “do no harm” has been central to medical ethics. The principle of beneficence refers not only to the avoidance of harm, but also to the obligation that a project facilitate and maximize the possible benefits to participants. Avoiding harm while simultaneously maximizing benefits often involves taking measured risks, weighing whether the potential benefits justify the potential risks of harm. Assessing the relative benefits and risks of a project requires knowledge and judgment, and such thoughtful, informed forethought is therefore an obligation of anyone who collects information from or
conducts research with human subjects. As much as possible, subjects should be given the informed opportunity to weigh risks and benefits for themselves. Altruism is among the motives for participating in a study, and with case study interviews, one benefit may be the opportunity for participants to share their stories.

**Justice**

If benefits must be weighted against risks, how should these benefits and risks be fairly distributed? Justice requires that people who participate in research should not unduly bear the burdens of such participation, especially if the benefits accrue primarily to others. Questions of justice arise both with individuals and with groups. For example, if a group becomes an object of study because of the convenience of its availability, the question must be raised of whether the participants in the study will also be the beneficiaries of its benefits.

**CODIFICATIONS OF INFORMED CONSENT BY SCHOLARLY PROFESSIONAL ORGANIZATIONS**

The general principles described in the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report require specific interpretation within the particular contexts of different academic disciplines. Comparison of how the principle of informed consent is interpreted across different disciplines serves to highlight the kinds of consideration a researcher needs to bring in developing appropriate informed consent procedures for a particular project. While there are important commonalities across discipline-specific codes, there are also important differences. Four such codes are briefly described here:

The American Psychological Association revised its code of ethics in 2002. The basic principle of informed consent is affirmed thusly:

“When obtaining informed consent..., psychologists inform participants about (1) the purpose of the research, expected duration, and procedures; (2) their right to decline to participate and to withdraw from the research once participation has begun; (3) the foreseeable consequences of declining or withdrawing; (4) reasonably foreseeable factors that may be expected to influence their willingness to participate such as potential risks, discomfort, or adverse effects; (5) any prospective research benefits; (6) limits of confidentiality; (7) incentives for participation; and (8) whom to contact for questions about the research and research participants' rights. They provide opportunity for the prospective participants to ask questions and receive answers.” [American Psychological Association Code of Ethics, Section 8.02.1, 2002]

The American Anthropological Association, reflecting its disciplinary focus, includes discussion of the need to tailor informed consent to the country or community in which the research occurs:

“Anthropological researchers should obtain in advance the informed consent of persons being studied, providing information, owning or controlling access to material being studied, or otherwise identified as having interests which might be impacted by the research. It is understood that the degree and breadth of informed consent required will depend on the nature of the project and may be affected by requirements of other codes, laws, and ethics of the country or community in which the research is pursued. Further, it is understood that the informed consent process is dynamic and continuous; the process should be initiated in the project design and continue through implementation by way of dialogue and negotiation with those studied... Informed consent, for the purposes of this code, does not necessarily imply or require a particular written or signed form. It is the quality of the consent, not the format, that is relevant.” [Code of Ethics of the American Anthropological Association, Section A.4, 1998]

Guidelines from the Oral History Association may be of particular relevance to the development of case studies, because data collection for developing case studies is often similar to collecting an oral history. Moreover, in the United States, the Office of Human Research Protections has specifically identified oral histories as lying outside the domain of regulations concerning the formal review of human research. That does not lessen the need for informed consent, which is specifically mentioned in the Evaluation Guidelines: "Has the educator:.....Ensured that each student is properly prepared before going into the community to conduct oral history interviews, including familiarization with the ethical issues surrounding oral history and the obligation to seek the informed consent of the interviewee? Has the student: Explained to the interviewee the purpose of the interview and how it will be used and obtained

The Code of Ethics of the American Sociological Association contains detailed guidelines for dealing with a variety of situations, based the core principle of informed consent:

“Informed consent is a basic ethical tenet of scientific research on human populations. Sociologists do not involve a human being as a subject in research without the informed consent of the subject or the subject’s legally authorized representative, except as otherwise specified in this Code. Sociologists recognize the possibility of undue influence or subtle pressures on subjects that may derive from researchers’ expertise or authority, and they take this into account in designing informed consent procedures.” [American Sociological Association, Code of Ethics, 1999] Among the exceptions recognized by the American Sociological Association is when the research involves observation of “public” actions.

These different ethics codes reveal that disciplines have distinctive points-of-view that mold how researchers view the informed consent process. At the same time, the agreement among these codes on the centrality of informed consent is striking. The perspective may vary, but informed consent is essential for ethical research across widely varying disciplines.

**AUTONOMY AND INFORMED CONSENT**

There are ethical issues involved in informed consent that are nuanced, complex and difficult to resolve, and researchers who study human subjects can benefit from more detailed guidance than the Belmont principles. Faden and Beauchamp [1986] have described three conditions of autonomous action necessary for informed consent: intentionality, understanding, and noncontrol. Application and interpretation of these principles in applying standards for informed consent will be discussed in the framework of three questions, each linked, respectively, to one of the Faden and Beauchamp [1986] conditions.

**WHAT DOES “CONSENT” MEAN?**

Before people can give meaningful informed consent, they must be “competent” to do so. There are degrees of competency, perhaps best illustrated by research with children. When research is conducted with minors, formal consent should be obtained from the child’s parent or guardian. However, obtaining consent from the child’s representative does not obviate the researcher’s obligation to obtain informed assent from the child himself or herself, with a level of information and a level of decision-making appropriate for the child’s age and level of cognitive development. For example, a child whose guardian has given informed consent for participation in an interview project about the child’s perception of day-care workers might be asked for informed assent in a limited, age-appropriate way: “I would like to ask you some questions about how you spend your day with Ms. Jones. Is that OK with you?”

Similar considerations apply with people with cognitive impairments or other disabilities that make it appropriate (indeed, essential) first to obtain consent from the subject’s representative. Moreover, a person’s competency can vary across different domains. For example, a cognitively challenged individual may be competent to decide about diet and exercise, but not about financial matters. In collecting oral histories or case study information, a researcher has an obligation to be sensitive to what domains of competency are at issue, as well as the subject’s degrees of competency within those domains. Respect for persons requires that an individual who lacks competency in certain domains not be treated as though lack of competency is a global trait that extends through all domains.

Consent decisions may be unstable over time. That is, a person who gives consent at one time may decide to withhold consent at a later time. Under most circumstances, such changes in consent should be respected. In particular, research participants should be told, and, if appropriate, reminded, that they can withdraw their participation at any time without penalty. There are some exceptional situations where the right to withdraw at any time may be limited, as when a patient agrees to a medical treatment that, once started, cannot be stopped without harm to the patient, and in such cases the subject must fully understand this constraint before giving consent.
WHAT DOES “INFORMED” MEAN?

To be informed, someone must not merely be provided information, but the person must understand the information and its implications. Effective communication is essential, and the communication must be tailored to be effective for the particular research subject. Clear wording, avoiding jargon, is essential.

Sometimes information must be withheld from a subject because of the research design. For example, in a case study of how a student reacts to a new teaching strategy, a detailed explanation of the strategy and its intended purpose may affect how the student reacts, invalidating the research. In such cases, the research design may justify the use of mild deception in the informed consent process, such as misleading the subject about the nature of the research. Usually, it is still possible to give the subject some information, such as, “we will not tell you all the purposes of the study until it is concluded, so as not to affect the results.” The use of deception, particularly deception that leads the subject to feel she or he was not treated fairly, damages the reputation of research in general, so any use of deception, even very mild deception, should be sparing and necessary for the research to be valid.

The way that information is framed can strongly influence a subject’s decision, particularly when there are risks and benefits to be weighed against one another [Tversky and Kahneman, 1981; Kahneman and Tversky, 1984]. Researchers should have the competence to identify when framing effects may affect decisions regarding informed consent, and they should take steps to provide information in a way that recognizes that such framing effects occur. For example, because people generally make choices that minimize losses, framing a description of a study in terms of possible losses may bias the subject to decline to participate, while framing the same study in terms of potential gains may bias the subject to consent. No single frame is the “correct” one, so a reasonable strategy for researchers is to provide the same information redundantly, in multiple frames.

Competent, cogent people often misunderstand, misinterpret, fail to pay attention, or forget aspects of what they have been told. When the consequences of participating in a study are anything other than exceedingly benign, it is wise for the researcher to include, as part of the study, an assessment of whether and what the subject understands about the nature of the study. Such assessment can be essential to establishing that the subject was truly informed, rather than merely provided information.

WHAT PRESSURES DISTORT AND UNDERMINE INFORMED CONSENT?

Consent provided under coercion is not voluntary. Thus, informed consent should be obtained without coercion, or perception of coercion.

In some situations, coercion is an inherent aspect of the situation. An obvious instance is when subject is a prisoner, and, in the United States, special regulations apply to research with prisoners, in recognition of the special problems in obtaining voluntary informed consent from prisoners. However, many other situations can involve coercion, perceived coercion, or an imbalanced power relationship between researcher and subject. An adult, for example, is in a special power relationship when dealing with a child, while a teacher bears a power relationship over students, a supervisor over employees, a physician over patients.

Subjects can lack control for reasons other than coercion or inappropriate use of power. The selection of exactly what information will be provided to potential subjects is controlled by the researcher, and incomplete or biased information can unduly influence a subject’s decision about consenting to participate. While, in general, more information is better than less, there is also a tension that arises because subjects may pay less attention and miss important facts if they are inundated with too much information. Anyone collecting information for a case study has a professional responsibility to be competent in communicating information to potential subjects in ways that are clear, salient, and comprehensible.

CONFIDENTIALITY, ANONYMITY, AND PRIVACY CONSIDERATIONS

To protect privacy, research subjects are often offered, as part of the informed consent process, assurances about confidentiality and/or anonymity. Privacy involves “the choice of the individual as to what he shall disclose and withhold, and when he shall do so...,” and informed consent is therefore key to the respect for privacy [Ruebhausen & Brim, 1966]. While behaviors that are clearly public can be studied
without informed consent (particularly when the fact that observations are being made is also clearly observable publicly), people differ in their perceptions of what actions are private and what actions are public. Informed consent is one means of making sure that researchers and their subjects perceive the boundary between what is public and what is private in the same way.

Private actions can become public through the publication or other dissemination of research. When the reported actions were private when they took place, researchers should have the informed consent of the subjects for making the information public in a case study. Some information can specifically be identified as “confidential,” not to be released by the researcher. Other information may be designated for release, but in a form that protects the anonymity of the person involved. For example, in case studies, names and other identifying information are sometimes omitted or fictionalized to protect privacy by keeping information confidential by means of anonymity.

Confidentiality, anonymity, and privacy are particularly salient issues for scholars developing case reports or case studies, because the effectiveness of cases often depends on the verisimilitude that is afforded by the inclusion of seemingly trivial details. The selection of which details to include and which to mask (e.g., with pseudonyms or with fictional distortions) can affect how the reader interprets the study. Case method has been criticized for the biases and values that can either deliberately or inadvertently be built into the narrative structure of a case study, and there are well-know examples, including the case of Anna O., which played a key role in the development of psychoanalysis [Ellenberger, 1972; Borch-Jacobsen, 1996] where liberties taken putatively to conceal the identity of the patient may have distorted the case report in serious and misleading ways.

Similar considerations arise when a case report is a “composite” of a pool of cases. The line between fact and fiction can grow murky, and research integrity can be threatened by well-intended actions taken to protect the confidentiality and to assure anonymity of human subjects. In such cases, the ethics of protecting participants may come into conflict with those of protecting the integrity of the data.

Seemingly trivial changes (e.g., using fictional names or locales), designed to hide the identity of the subjects, may not be so trivial in the eyes of some observers. For example, names of people, including fictional names, often signal ethnic background, and changing the identification of the locale of the study may frame its interpretation (e.g., people are known to act differently in Tulsa from the way people act in New York). Thus, it is generally better to protect anonymity by providing only general information (e.g., “the incident took place in a medium-sized city on the West Coast of the United States”), rather than by fictionalizing parts of the report. The steps taken to assure protection of privacy can be specified in advance in the informed consent process, so subjects are told exactly how their identities will be kept hidden. And if the author of a case study does resort to fictionalizing portions of the report in order to protect identities, this practice should be explicitly described in the report (e.g., “names have been changed but other details are factual”).

Some case studies may involve the possibility that subjects may reveal information that ethically should and legally must be reported to law enforcement agencies. For example, this may occur if a subject reveals a threat of child abuse. The need for the researcher to report such information can be stated explicitly in an informed consent process, so the subject can decide whether or not to participate, with a full understanding of the limits on any promised confidentiality or anonymity.

CROSS-CULTURAL CONSIDERATIONS

Ethical codes developed in Europe and in the United States reflect beliefs and attitudes characteristic of the cultures in which they were developed. For example, the concept of individual autonomy is central to many of the ethical considerations involved in informed consent, yet different cultures differ considerably in the extent to which people are viewed as individual, independent agents or as members of a collective, such as a family, a team, a tribe, or a nation [Triandis, 1995]. Such cultural variation means that the implementation, and even the value, of informed consent may vary among cultures. Procedures that are appropriate for obtaining informed consent in the United States or in Western Europe may need to be modified considerably to make them appropriate, comprehensible, and consonant with the values of human subjects in other cultural contexts. That may require informing groups as well as individuals in cultures where there is strong group identity. For example, in some cultures it may be appropriate to seek informed consent from an entire family rather than solely from the individual being
studied, or it may be appropriate to seek permission from other family members as well as the parents when children are studied.

The range of cultural variation is so large that no simple rules can assure a culturally-appropriate use of informed consent. Researchers must make complex, informed judgments that require that they have the training and background in the ethical principles, in the nature of cultural variation, and in the specific nature of the local culture they are studying. There is an ethical responsibility for researchers not only to have the background knowledge and competence to judge what local understandings of autonomy, privacy, and confidentiality are, but also to understand the researcher’s own ethnocentric perspectives and biases. There are many political shoals to be navigated in the ethics of cross-cultural research [Warwick, 1980], and people conducting research for case studies need to be highly aware of these issues. When people are poor, illiterate, and unfamiliar with research, special care should be taken to assure that subjects are not manipulated or coerced by people in authority.

When scientists covered by U.S. laws and regulations conduct research in other countries, the procedures followed for protection of human subjects (including the obtaining and documenting of informed consent) can follow procedures different from those that would be employed in the United States, so long as those procedures afford "equivalent protection" to that afforded by U.S. regulations. For example, in countries where research protections follow different procedures (e.g., at institutions outside the U.S. that use the Declaration of Helsinki as a basis for research protections), U.S. researchers can follow the local procedures, providing they provide an "equivalent protection." This policy has come under scrutiny and criticism in recent years, primarily in the domain of medical research. (For example, what constitutes "equivalent protection" in countries where the standard of care is different from that in the U.S.?) As a result, the Office of Public Health and Science, Department of Health and Human Services, is currently in the process of developing criteria for determining when "equivalent protection" has been achieved.

CONSIDERATIONS WHEN INFORMED CONSENT CANNOT BE OBTAINED

Informed consent can be obtained from individuals, but what should be done when an entire community is the object of the research? For example, a researcher may develop a case study of how a particular community reacts to a natural disaster, of how an organization reacts to an increase in funding, or of how a neighborhood responds to a plant closing. Informed consent both from individuals and from organizations representing the group as a whole, or components of the group, are all appropriate in such cases, especially when the report involves information that would not otherwise be made public.

Research subjects who are deceased obviously cannot give informed consent. Most codes of research apply to living human subjects, but there are also ethical issues involving informed consent that should be considered when case reports contain information about people who have died, and controversies over these issues can and do erupt (e.g., when Diane Middlebrook, a biographer of the poet Anne Sexton, was given access to tapes of Sexton’s psychiatric sessions with Martin Orne).

SHOULD GUIDELINES CONCERNING INFORMED CONSENT APPLY TO ALL HUMAN RESEARCH?

There is concern in the United States about whether federal regulations designed to protect human subjects are being too broadly applied [Gunsalus, 2002; Sieber, Plattner, and Rubin, 2002; Nelson, 2003]. For regulatory purposes, research is defined as “as systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge…” This definition is so broad that most academic work could be construed as meeting it. Recently, the Office of Human Research Protections has issued a letter indicating that oral histories do not have to undergo the mandated review process for human research projects, but this ruling leaves unclear which other kinds of research, similar to oral histories, might also not fall under the review requirement. Regardless of how the regulatory controversies play out, all researchers have an ethical obligation to respect and protect the people they study, so the principles of informed consent are relevant whether or not a research project is construed as requiring formal review.

Are case studies scholarship? To the extent that they are, they should conform to the ethical principles and guidelines that are relevant, across disciplines, to research with human subjects. The principle of informed consent, whether considered as a formal requirement in a research project or as a
key ethical consideration in other kinds of scholarship, is central to ethical scholarship involving humans. Informed consent should be a routine aspect of the collection of information in developing a case study, whether the case study is intended a research project, a pedagogical tool, or a combination of the two.

REFERENCES


